# Creatinine Standardization Program

## Recommendations for National Metrology Institutes, Reference Laboratories, and JCTLM Organizational Members*

The National Kidney Disease Education Program (NKDEP), in collaboration with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the European Communities Confederation of Clinical Chemistry (EC4), has launched the Creatinine Standardization Program to reduce inter-laboratory variation in creatinine assay calibration and provide more accurate estimates of glomerular filtration rate (GFR). The effort is part of a larger NKDEP initiative to help healthcare providers better identify and treat chronic kidney disease in order to prevent or delay kidney failure and improve patient outcomes.

National metrology institutes, reference laboratories, and JCTLM organizational members are crucial partners in the successful implementation of this program. The following steps are necessary to ensure a smooth transition from traditional calibration to calibration that is traceable to an isotope dilution mass spectrometry (IDMS) reference method:

1) Provide tools to assist IVD manufacturers to reduce analytical bias.
2) Develop readily available reference materials for serum creatinine with IDMS assigned values and with validated commutability with individual patient sera for a wide variety of routine methods. The reference materials should be submitted to Joint Committee for Traceability in Laboratory Medicine (JCTLM) for review and acceptance. National Institute for Standards and Technology (NIST) SRM 967 [two levels, approximately 66 µmol/L (0.75 mg/dL) and 347 µmol/L (3.92 mg/dL)] is expected to fulfill this need and to be available in mid-2006.
3) Make available a high-level reference measurement procedure with high throughput to assist IVD manufacturers in validating the trueness of their methods, and to assist in validating commutability of candidate reference materials. A LC-IDMS procedure validated to have little or no bias relative to GC-IDMS may be useful for this purpose.
4) Additional reference laboratories are needed to meet the anticipated demand for analytical services to establish and validate traceability to the reference method.

More information about the Creatinine Standardization Program and recommendations for other groups, including clinical laboratories and IVD manufacturers, can be found at www.nkdep.nih.gov/labprofessionals.

**Contact Information**

For assistance, please contact us at csp@info.niddk.nih.gov or call 301-435-8116.

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